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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	4

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/543,782	ZUCKER-FRANKLIN AND PANCAKE
Examiner	**Art Unit**
CB Wilder	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Apr 9, 2001*.

2a) ☐ This action is **FINAL.** 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-10* is/are pending in the application.

4a) Of the above, claim(s) *3-10* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *1 and 2* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) X Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)	Notice of References Cited (PTO-892)	18)	Interview Summary (PTO-413) Paper No(s).
16)	Notice of Draftsperson's Patent Drawing Review (PTO-948)	19)	Notice of Informal Patent Application (PTO-152)
17)	Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20)	Other

FINAL ACTION

1. Applicant's amendment filed April 9, 2001 in Paper No. 7 is acknowledged. Claims 1 has been amended. Claims 1 and 2 are pending. The arguments have been thoroughly reviewed, but are not found persuasive for the reasons that follows. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

This Action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. Applicant's election with traverse of Group I, claims 1 and 2 in Paper No. is acknowledged. The traversal is on the ground(s) that all of the claims are directed to a method for screening by identifying a *tax* protein. Applicant further argues that since it is assume that the Examiner will search online rather than manually, and will search the SEQ ID NOS: online, a search which encompasses the DNA and method of making some would also include methods of using the enzyme. Applicant believes this is no serious burden to the Examiner. Applicant further argues that if the restriction is maintained, it will be clear on the record that the PTO considers the two groups to be patentably distinct from one another, *i.e.*, *prima facie* non-obvious from one another. Applicant argues that this means that a reference identical to the one group would not render the other group *prima facie* obvious. This is not found persuasive because the searches for

the different Groups I-III are not coextensive in the prior art because methods of screening DNA are not required or necessary for methods of screening for protein or an antibody. Additionally different methods steps are required for analyzing DNA versus protein or an enzyme. Since the Applicant has already elected Group I, claims 1 and 2, the non-elected claims which encompasses a protein or antibody are excluded and withdrawn from prosecution.

With respect to Applicant's argument concerning the two groups being patentably distinct and a reference identical to the one group not rendering the other group *prima facie* obvious, the Examiner would like point out to Applicant that patentably distinct inventions are examined independently of each other.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of the inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

The requirement is still deemed proper and is therefore made FINAL.

Previous Rejections

4. The claim rejection under 35 U.S.C. 112 second paragraph are withdrawn in view of Applicant's amendment. The prior art rejections under 35 U.S.C. 102(b) directed to claims 1 and 2 as being anticipated by Zucker-Franklin et al. is maintained and discussed below.

Claim Rejections - 35 USC § 102

5. Applicant's attention is once again drawn to 35 U.S.C. 102(b). Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker-Franklin et al. *(Proc. Natl. Acad. sci. USA, vol. 94 (12):6403-6407, June 1997).* Regarding claims 1 and 2, Zucker-Franklin et al. teach a method of screening blood donors or potential blood donors for carriers of diseases or conditions related to HTLV-I and/or HTLV-II infection, comprising: subjecting each blood sample from the donors or potential donors to a test for the presence of DNA encoding the HTLV-1 and/or HTLV-II Tax protein and determining that the donor is a carrier of a disease or condition related to HTLV-I and/or HTLV-II infection when said subjecting step is positive, without input from any other test results or screening test specifically provided to test for infection with either HTLV or HTLV-II (col. page 6404, columns 1, beginning at line 4 to col. 2 line 16, *see also page 6405, col. 1, lines 17-37*). Therefore the claimed invention of claims 1 and 2 is anticipated by the reference of Zucker-Franklin et al.

6. Applicant amendment filed in Paper No. 7 have been thoroughly reviewed and considered but they are not found persuasive for the reasons that follow. Applicant traverses the rejection on the following grounds: Applicant argues that the cited reference does not teach the instant invention because the sera tested in the description on page 646 had tested negative for antibodies to HIV as disclosed at page 6404 left column, line 3. Applicant further argues that in addition, at page 6405, the individuals tested were HIV-negative methadone clinic attendees. Applicant argues that indeed, among the 63 individuals who were not expected to be HTLV-infected on the basis of standard serologic tests, there were seven whose cell lysates on PCT/Southern blot

revealed gag-I and/or pol-I in addition to tax sequences (Table 2). Applicant argues that there is nothing in Zucker-Franklin et al. that suggest that the test be used in the absence of any other testing, only that the tax test has been found to identify HIV infection where other test have found no identification of infection. Applicant argues that indeed on page 6406, it is suggested that the inclusion of Tax in serologic test kits or more sensitive techniques incorporating simultaneous amplification of several relevant nucleic acid sequences by an automated system has been suggested elsewhere could be introduced to screen our blood supply for HTLV more reliably. Applicant argues that the present inventors have concluded, based upon testing if blood and other bloodily fluids, that there is no requirement for input from any other test result to test positively for HTLV-I and/or HTLV-II. Applicant concludes that the claims are now in condition for allowance and a favorable action thereon is earnestly solicited.

7. The arguments have been fully considered but are not found persuasive for the following reasons: First the courts have established that during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. (see *In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed Cir, 1989).* In this case, the broadly claimed limitation "without input from any other test results" can be interpreted as meaning "without input from any other test results from other methods such as from an ELISA or Western blot assays" or etc. not necessarily as Applicant argues by the addition of gag or pol to the tax sequence. Additionally, in contrast to Applicant's arguments, the cited reference do teach wherein a test was performed on the tax sequence alone and a positive test for HTLV-II was indicated (see Table 2). Likewise, the reference specifically teaches at page 6405, column 1 that "among HIV-negative methadone

clinic attendees, the largest number of infected individuals were indentified when HTLV-I/II Tax primers and probes were used in PCR/Southern blot analysis". This further supports the claimed limitation of the instant invention. With respect to Applicant's arguments concerning testing negative for antibodies to HIV as disclosed in the reference, the arguments are irrelevant because Applicant is arguing a non-elected limitation of the instant invention. The arguments are not sufficient to overcome the prior art rejection. Accordingly, the rejections are maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTION WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 1 and 2 are incomplete and indefinite because the claims lack an essential step which renders the claims confusing. There is no step wherein the blood sample from the donors are tested for the presence of a DNA which encodes the HTLV-I Tax protein. Therefore, it is unclear how the step of final step is achieved without an initial step for the screening.

(b) Claims 1 and 2 lack proper antecedent basis for " "said subjecting step is positive" in claim 1 because the prior steps do not recite "a subjecting step".

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The Examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

Cynthia B. Wilder, Ph.D.

June 14, 2001